

Application No.: 10/802395
Filing Date: March 17, 2004

REMARKS

Claims 1-41, 54-61, 63, 68, and 74 were before the Examiner for consideration in this application. In this paper, Claims 54, 61, and 74 have been amended, no claims have been added, and no claims have been canceled. Accordingly, Claims 1-41, 54-61, 63, 68, and 74 remain before the Examiner for consideration. No new matter has been added with this amendment.

Summary of the Office Action

The Office Action rejects: Claims 1-4, 23-25, and 36-39 under 35 U.S.C. §102(b) as anticipated by Melican et al. (U.S. Patent No. 6,599,323); Claims 5-13, 26-27, 40-41 under 35 U.S.C. §103(a) as unpatentable over Melican et al. in view of Shaw et al. (U.S. Patent No. 5,879,366); Claims 14-19 under 35 U.S.C. §103(a) as unpatentable over Melican in view of Notaras et al. (WO 9603091); Claims 20-22 and 54 under 35 U.S.C. §103(a) as unpatentable over Melican in view of Clubb et al. (U. S. Patent No. 7,323,001); and Claims 28-35, 54-61, 63, and 68 under 35 U.S.C. §103(a) as unpatentable over Melican et al. in view of Shaw et al. (U.S. Patent No. 5,879,366) and further in view of Hill et al. (US Patent Application Publication No. 2003/0060871). For the reasons discussed below, Applicant respectfully traverses these rejections.

Regarding Claim 1

The present application is a continuation-in-part of U.S. Application Serial No. 09/435,562, which was filed on November 8, 1999. The subject matter of Claim 1 finds support from the '562 application. Accordingly, Claim 1 is entitled to the benefit of the filing date of the '562 application. See M.P.E.P 201.11 (I) (B). Therefore, Melican, which has a publication date of August 29, 2002, and a filing date of December 21, 2000, is not available as a prior art reference.

Furthermore, Claim 1 of the present application recites a biocompatible laminate fabric comprising, among other limitations, a porous first membrane layer, a porous second membrane layer, and an open mesh bonding layer between the first and second membrane layers. The bonding layer holds the first and second membrane layers together by "*extending into* one or

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more pores of each membrane layer." (Emphasis added). In contrast to the recited laminate fabric, Melican fails to disclose at least a *bonding* layer. Melican relates to a biocompatible tissue implant device including one or more layers of polymeric foam having pores and a *reinforcement component* preferably in the form of the mesh fabric. (Col. 3, lines 3-12). Thus, Melican discloses a tissue implant having a reinforcement component, but no bonding layer. Further, Melican's reinforcement layer does not "extend into" pores of adjacent membrane layers to hold the first and second membrane layers together, as is recited in Claim 1. Rather, in the Melican implant the "web or walls 11 of the foam component that form pores 13 penetrate the mesh of the reinforcement component 14 and interlock with the reinforcement component". (Col. 3, lines 54-57). Accordingly, for at least these reasons, Melican fails to disclose the laminate fabric recited in Claim 1.

Claims 2-35 depend from Claim 1 and recite additional novel and nonobvious limitations thereon. As indicated, various groups of claims within Claims 2-35 were rejected as being anticipated by Melican or obvious over Melican in combination with various other references. Regarding these other references, neither Shaw nor Notaras nor Clubb nor Hill disclose a bonding layer that "extends into" pores of adjacent membrane layers as is recited in Claim 1. Accordingly, the various combinations references suggested by the Office Action fail to disclose all of the limitations recited in Claim 1 from which Claims 2-35 depend.

Regarding Claim 36

Claim 36 is fully supported by the parent '562 application, as well. Accordingly, for the reasons discussed above with respect to the priority of Claim 1, Melican is not available as a prior art reference to Claim 36 either.

Furthermore, Claim 36 recites, among other limitations, an implantable medical device comprising a biocompatible laminate comprising a porous first membrane layer, a porous second membrane layer, and an open mesh bonding layer between the first and second membrane layers. The bonding layer "holds the first and second membrane layers together by extending into one or more pores of each membrane layer." As discussed above with respect to Claim 1, Melican fails to disclose a bonding layer or a bonding layer that extends into pores of adjacent membrane

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layers. Thus, for at least the reasons discussed above with respect to Claim 1, Melican fails to anticipate the implantable medical device of Claim 36, as well.

Claims 37-41 depend from Claim 36 and recite additional novel and nonobvious limitations thereon. As indicated above, various groups of claims within Claims 37-41 were rejected as being anticipated by Melican or obvious over Melican in combination with Shaw. Shaw does not disclose a bonding layer that "extends into" pores of adjacent membrane layers as is recited in Claim 1. Accordingly, the various combinations references suggested by the Office Action fail to disclose all of the limitations recited in Claim 36 from which Claims 37-39 depend.

Regarding Claim 54

Claim 54 relates to a composite membrane comprising, among other limitations, a first membrane, a second membrane, and the mesh bonding layer. The bonding layer at least partially "extends into" membrane pores of the first membrane and the second membrane. The composite membrane has "a composite membrane open surface area in the range between about 10% and about 50%." The Office Action rejected Claim 54 under 35 U.S.C. § 103(a) as being unpatentable over Melican in view of Clubb. As discussed above with respect to Claim 1, Melican fails to disclose composite membrane including a *bonding* layer between a first membrane and a second membrane, or a bonding layer that extends into membrane pores. Clubb likewise fails to disclose such a bonding layer.

Furthermore, the Office Action indicated that Clubb teaches the mesh element has a present open area *greater than 50%*, which is outside the recited range of between "about 10% and about 50%". Accordingly, this combination of references does not appear to disclose all of limitations recited in Claim 54.

The Office Action also rejected Claim 54 under 35 USC §103(a) as being unpatentable over Melican in view of Shaw further in view of Hill. As noted above with respect to Claim 1, Melican fails to disclose a bonding layer between two membrane layers that extends into pores of the two membrane layers. Shaw and Hill likewise fail to disclose a bonding layer, as claimed.

Further, the Office Action indicates that both Melican and Shaw fail to disclose a composite membrane open surface area in the recited range. Hill likewise fails to disclose the

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recited membrane open surface area. Hill discloses a multi-layered tubular structure suited for use as an endoprosthesis or vascular graft. (Paragraph [0020]). An inner tubular member and an outer tubular member can have different porosity, one selected to provide strength and the other selected to provide transport of bioactive agents therethrough. (Paragraph [0023]). Hill likewise discloses various embodiments having different internodal distances of the outside and inside layers of the tube structure. (Paragraphs [0071]-[0084]). However, Hill fails to disclose the membrane open surface area of these embodiments. Hill further fails to indicate other geometric properties of the graft that would allow calculation of the open surface area.

Accordingly, for at least the reasons discussed above, Claim 54 distinguishes over the asserted reference combinations. Claims 55-60 depend from Claim 54 and recite additional novel and nonobvious limitations thereon. Accordingly, Claims 55-60 distinguish over the applied art for at least the reasons discussed above with respect to Claim 54.

Regarding Claim 61

Claim 61 recites a laminated medical device comprising, among other limitations, a frame, a first membrane, a second membrane, and the mesh bonding layer. The bonding layer at least partially “extends into” membrane pores of the first membrane and the second membrane to form a composite membrane. The composite membrane has “a composite membrane open surface area in the range between about 10% and about 50%.”

The Office Action rejected Claim 61 under 35 U.S.C. §103(a) as unpatentable over Melican in view of Shaw further in view of Hill. For at least the reasons discussed above with respect to Claim 54, Claim 61 also distinguishes over the applied art. Claims 63 and 68 depend from Claim 61 and recite additional novel and nonobvious limitations thereon. Accordingly, Claims 63 and 68 distinguish over the applied art for at least the reasons discussed above with respect to Claim 61.

Regarding Claim 74

Claim 74 recites a stent comprising, among other limitations, a frame configured for use as a stent, a first membrane, a second membrane, and the mesh bonding layer. The bonding layer

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at least partially “extends into” membrane pores of the first membrane and the second membrane to form a composite membrane.

The Office Action rejected Claim 74 under 35 U.S.C. §103(a) as unpatentable over Melican in view of Shaw further in view of Hill. For at least the reasons discussed above with respect to Claim 54, Claim 74 distinguishes over the applied art, as well.

Conclusion

In light of the above comments, Applicant respectfully submits that all of the pending claims are allowable over the cited art. Applicant therefore requests that the Examiner issue a Notice of Allowability at the Examiner’s earliest convenience.

No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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AMEND

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